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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,722	04/23/2001	Michael C. MacLeod	UTSC:607USC1	5071

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/12/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/840,722	MACLEOD ET AL.
	Examiner Ethan Whisenant, Ph.D.	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 November 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3,4,20,21,23-29,36-76 and 85-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 3,4,20,21,23-29,36-49,52-76,85 and 87-89 is/are rejected.
- 7) Claim(s) 50,51 and 86 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> .	6) <input type="checkbox"/> Other: _____

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DETAILED ACTION

1. The applicant's Response (filed 25 NOV 02) to the Office Action has been entered. The applicant's response has been entered as paper no. 09. The claims pending in this application are **Claim(s) 3-4, 20-21, 23-29, 36-76 and 85-89**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

6. **Claim(s) 87-89** is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Senapathy [US 5,994,058 (1999)].

Claim 87 is drawn to a primer molecule comprising a predetermined 5' sequence for annealing to a linker sequence and a 3' terminal specificity region of from 3-8 nucleotides in length, the specificity region defined as one of all possible sequence combinations A,T,G or C.

Senapathy teaches such a primer molecule. See, for example Figure 1. Admittedly, this author does not teach that their primer will anneal to a linker sequence. However this limitation is considered to be inherent to primer of Senapathy. If an appropriate linker sequence is provided then the primer of Senapathy will anneal. Regardless, this limitation is directed towards the intended use of the primer. It is well established that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it

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meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim 88 is drawn to a population of primer molecules wherein the primer molecules comprise a predetermined 5' sequence for annealing to a linker sequence and a 3' terminal specificity region of from 3-8 nucleotides in length, wherein the population of primer molecules comprise specificity regions collectively reflecting all possible sequence combinations A,T,G or C. **Claim 89** is drawn to a primer molecule selected from the population of primer molecules of Claim 88.

Senapathy teaches such a population of primer molecules. See, for example Figure 1. Admittedly, this author does not teach that their primer(s) will anneal to a linker sequence. However this limitation is considered to be inherent to the population of primer molecules of Senapathy. If an appropriate linker sequence is provided, then the primer of Senapathy will anneal. Regardless, this limitation is directed towards the intended use of the primer. It is well established that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

7. **Claim(s) 87-89** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Silver et al. [US 5,104,792 (1992)].

Claim 87 is drawn to a primer molecule comprising a predetermined 5' sequence for annealing to a linker sequence and a 3' terminal specificity region of from 3-8 nucleotides in length, the specificity region defined as one of all possible sequence combinations A,T,G or C.

Silver et al. teach such a primer molecule. See, for example Figure 1. Admittedly, these authors do not teach that their primer molecule will anneal to a linker sequence. However this limitation is considered to be inherent to primer of Silver et al. If an appropriate linker sequence is provided then the primer of Silver et al. will anneal. Regardless, this limitation is directed towards the intended use of the primer. It is well established that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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Claim 88 is drawn to a population of primer molecules wherein the primer molecules comprise a predetermined 5' sequence for annealing to a linker sequence and a 3' terminal specificity region of from 3-8 nucleotides in length, wherein the population of primer molecules comprise specificity regions collectively reflecting all possible sequence combinations A,T,G or C. **Claim 89** is drawn to a primer molecule selected from the population of primer molecules of **Claim 88**.

Silver et al. teach such a population of primer molecules. See, for example Figure 1. Admittedly, these author do not teach that their primer(s) will anneal to a linker sequence. However this limitation is considered to be inherent to the population of primer molecules of Silver et al. If an appropriate linker sequence is provided, then the primer of Silver et al. will anneal. Regardless, this limitation is directed towards the intended use of the primer. It is well established that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

NONSTATUTORY DOUBLE PATENTING REJECTION

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. **Claim(s) 20, 3-4, 21, 23-29, 36-49, 52-76, 85 and 87-89** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim(s) 1, 3-4, 20-21, 23-29, 36-49, 52-77 and 85 of US 6,221,600 (2001). Although the conflicting claims are not identical, they are not patentably distinct from each other.

CLAIM OBJECTIONS

10. **Claim(s) 50-51, 86** is/are objected to because it is dependent upon a rejected independent base claim.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

11. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection. It is noted that the prior art rejections which relied on Lizardi [US 6,280,949 (2001)] in view of Kambara et al. [US 5,650,274 (1997)] have been withdrawn in view of the applicant's amendment and the arguments therein. In addition, the 102 rejection which used the B-M Catalog (1997) has also been withdrawn in view of the applicant's amendment and the arguments therein.

CONCLUSION

12. **Claim(s) 3-4, 20-21, 23-29, 36-76 and 85-89** is/are rejected and/or objected to for the reason(s) set forth above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

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The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



Ethan Whisenant, Ph.D.
Primary Examiner